UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: Environmental risk assessment for the FIFRA Section 3 registrations of the end use products Summit B.t.i. Mosquito Briquets (EPA File Symbol 6218-IT) and Summit Mosquito Bits (EPA File Symbol 6218-IA) containing the active ingredient *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 (PC Code: 006401); Decision Nos. 512467 and 509495; Submission Nos. 978993 and 974778; DP Barcode Nos. 431319 and 434993

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A. Background Information

Summit Chemical Company (hereafter "Summit") has applied for FIFRA Section 3 registration of two end use products (EPs), Summit B.t.i. Mosquito Briquets (EPA File Symbol 6218-IT) and Summit Mosquito Bits (EPA File Symbol 6218-IA, note: the proposed label lists "Summit Mosquito Bites" as the name), which contain the active ingredient (a.i.) *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 (hereafter "*Bti* SUM-6218"). Summit B.t.i. Mosquito Briquets contain 10.31% a.i., while Summit Mosquito Bits contain 2.86% a.i. Both are proposed for application directly to water to control mosquito larvae. Summit B.t.i. Mosquito Briquets are formulated as small briquettes, are intended to float on the water, and dispense the a.i. slowly over a period of approximately 30 days. They are proposed for application outdoors in water bodies or where water collects, or indoors in areas that collect water such as elevator shafts, sump pump areas, and other drainage areas. One briquette treats up to 100 square feet of surface area of standing water, and briquettes may be applied on dry areas prior to flooding. Summit B.t.i. Mosquito Briquets are also proposed for use in waste water treatment facilities to treat for psychodid fly larvae. Summit Mosquito Bits are a granular formulation, and sink when applied to water. For control of mosquitoes, Summit Mosquito Bits are to be applied at up to 20 lbs per acre of surface water, with 3 to 14 day application intervals. This product is also proposed to

control fungus gnats in soil. Both products have sublabels for "commercial/professional" uses and residential uses.

The manufacturing use product (EPA Reg. No. 6218-83) was previously registered. In the risk assessment for that product[1], EPA determined that exposure to nontarget organisms would not occur, and that additional consideration for nontarget exposure and a risk assessment would be necessary if any end use products containing *Bti* SUM-6218 were proposed for registration. The proposed registration of these two EPs constitutes significant new uses and a different exposure profile for *Bti* SUM-6218. Therefore, a review to assess the potential risks to nontarget organisms is needed.

B. Nontarget Effects Data

In its risk assessment for the manufacturing use product, EPA previously determined that the nontarget organism data requirements for *Bti* SUM-6218 had been satisfied. This active ingredient was determined to be identical to the bacterium originally isolated in Israel in 1977, which is the active ingredient in other registered *Bti* based pesticides. Since these a.i.'s are identical, studies currently available in EPA's database of nontarget studies on *Bti* can be bridged to *Bti* SUM-6218 to support the registration of the proposed EPs. To support the registration of the manufacturing use product, Summit cited several previously submitted studies with *Bti*, as well as scientific rationale. Summit also submitted a guideline study with *Daphnia magna* to further support bridging to data on the bacterium originally isolated from Israel and to show that heat labile exotoxins are not produced in the manufacture of their a.i. These data and other information were determined to be acceptable. They are also appropriate to support the registrations of the proposed new EPs. The data requirements for these new uses of *Bti* SUM-6218 have been met with acceptable data, and additional data are not required.

C. Ecological Risk Conclusions

In the 1998 *Bacillus thuringiensis* Reregistration Eligibility Decision (RED)[2], EPA concluded that risks to nontarget organisms exposed to *Bacillus thuringiensis* (including *Bti*) are unlikely as long as the presence of heat labile exotoxins or beta-exotoxins is minimized. In addition to information submitted to show that beta-exotoxins will not be produced (see reference in footnote 1), Summit provided EPA with an acceptable 21-day study on *Daphnia* (MRID 48682624, with supplemental information in MRIDs 48954200 and 48954201) to show that *Bti* SUM-6218 does not produce heat-labile exotoxins. This study was determined to be acceptable, and provides a satisfactory basis to make similar conclusions about *Bti* SUM-6218 that have been made for other *Bti* based pesticides.

As discussed above, *Bti* SUM-6218 also has been shown to be identical to the *Bti* originally isolated and registered with EPA. Therefore, bridging to previously submitted data and extending conclusions on nontarget organisms from the RED to the current proposed registrations are both

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[1] Memorandum from S. Borges to D. Greenway, subject: Environmental risk assessment for the FIFRA Section 3 registration of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218, dated April 17, 2013.
[2] USEPA. 1998. Reregistration Eligibility Decision (RED) *Bacillus thuringiensis*. EPA 738-R-98-004. Available at http://www.epa.gov/oppsrrd1/REDs/0247.pdf

possible. Based on these data and other information, adverse effects to nontarget organisms are not expected as a result of the proposed new uses of *Bti* SUM-6218 in the proposed new EPs, as labeled.

Bti SUM-6218 must be consumed to have insecticidal effect; contact with pesticide is not expected to cause effects. While exposure to nontarget organisms is possible with the proposed new uses, it is primarily expected to be limited to the treated wet and aquatic areas. The briquette formulation may be available briefly for terrestrial nontarget organisms prior to flooding; however, this formulation is not expected to be attractive to nontarget organisms as a food item. Therefore, based on the available data, EPA concludes adverse effects are not anticipated for nontarget organisms, including non-target mammals, birds, plants, freshwater and marine/estuarine animals, honeybees, and non-target insects outside of the taxonomic order Diptera. Since EPA has determined that no adverse effects are anticipated for these species a "No Effect" determination is made for direct and indirect effects to federally listed ("listed") endangered and threatened species of these taxa, and for their designated critical habitat.

While *Bti* is not expected to have effects on most nontarget insects, it is known to be active against species within the taxonomic order Diptera. The risk of adverse effects of *Bti* SUM-6218 non-listed dipteran insects is not non-existent, but it is expected to be relatively low and limited to early larval instars. Effects on listed individuals within the Order Diptera that occur in wet habitats and consume microbial *Bti* cannot be precluded. At present, listed dipteran species consist of picture-wing flies in Hawaii (all are *Drosophila* spp.) and the Delhi Sands flower-loving fly (*Raphiomidas terminatus abdominalis*). All of the picture-wing flies are terrestrial species whose larvae consume decaying material of one or a few specific host plants prior to dropping to the soil to pupate (USFWS 2006, 2010, 2013). Therefore, they are unlikely to be feeding in areas where *Bti* SUM-6218 in the proposed two new EPs would be applied, and they are unlikely to be exposed. The larvae of the Delhi Sands flower-loving fly specifically inhabit areas with fine sand and sparse vegetation (USFWS 1997). Since soils with high organic and moisture content give rise to pest problems with fungus gnats, sandy soils inhabited by the Delhi Sands flower-loving fly are not likely to be targeted for control of this pest with the Mosquito Bit EP. Therefore, this species is also unlikely to be exposed. Since exposure is not expected as a result of the proposed new uses associated with the proposed EPs, EPA makes a "no effect" determination for direct effects to listed dipteran species.

Indirect effects to species that are highly dependent on dipteran larvae as food cannot be precluded. Of the listed insects, these may potentially include species of damselfly or dragonfly from within Order Odonata whose larvae inhabit aquatic areas or terrestrial or semi-terrestrial areas and depend heavily on dipteran larvae. For insects with a narrow dietary range requiring mosquito larvae, reductions in larvae may have adverse effects on food resources. Since the applications of *Bti* SUM-6218 in the proposed EPs are associated with uses that cannot be easily defined geographically, further analysis is needed to make a determination about potential indirect effects to listed insects depending on dipteran larvae in their diet.

A list of a.i.'s in registered alternatives to products containing *Bti* for control of larval mosquitoes, fungus gnats, and psychodid flies is provided below (Table 1). This list includes conventional and biochemical pesticides that are labeled for the pests as the proposed EPs

containing *Bti* SUM-6218. Insect hazard likely differs between *Bti* SUM-6218 and these alternatives. However, insect hazard endpoints between chemical pesticides and viable or living microbial pesticides are not comparable, primarily because they are typically expressed in different units (i.e., mg/mL vs cfu/mL) and specific volumes or masses of microbial pesticides will not necessarily contain a consistent number of cells or colony forming units or consistent levels of pesticidal toxins (if produced). One consideration that may be made concerning environmental hazard and risk is the breadth of the activity spectrum. For example, *Bti* may adversely affect insects in Order Diptera. However, several pesticides listed below are known to have adverse effects to a wider spectrum of insect species and may be considered to have greater relative hazard to this group of nontarget organisms.

Table 1. Active ingredients in registered alternatives to products containing *Bti* SUM-6218 mosquito, fungus gnat, and psychodid fly larvae.

Ingredient Name	**Pesticide Type**
Mosquito	
Aliphatic petroleum solvent	Conventional
Bifenthrin	Conventional
Bt israelensis BMP 144	Microbial
Bt israelensis SA3A	Microbial
Diflubenzuron	Conventional
Malathion	Conventional
MGK 264	Conventional
Mineral oil	Conventional
POE isooctadecanol	Conventional
S-Methoprene	Biochemical
Fungus gnat	
Abamectin	Conventional
Azadirachtin	Biochemical
Bifenthrin	Conventional
Chlorpyrifos	Conventional
Cyfluthrin	Conventional
Permethrin	Conventional
Pyrethrins	Conventional
Psychodid fly	
Bt israelensis BMP 144	Microbial
Bt israelensis SA3A	Microbial

References

U.S. Fish and Wildlife Service (USFWS). 1997. Final Recovery Plan for the Delhi Sands Flower-Loving Fly. U.S. FWS, Pacific Region. 51 pp.

USFWS. 2006. Endangered and Threatened Wildlife and Plants; Determination of Status for 12 Species of Picture-Wing Flies From the Hawaiian Islands. Federal Register Volume 71, Number 89, May 9, 2006; pages 26835-26852.

USFWS. 2010. Endangered and Threatened Wildlife and Plants; Determination of Endangered Status for 48 Species on Kauai and Designation of Critical Habitat. Federal Register Volume 75, Number 70, April 13, 2010; pages 18960-19165.

USFWS. 2013. Endangered and Threatened Wildlife and Plants; Determination of Endangered Status for 15 Species on Hawaii Island. Federal Register Volume 78, Number 209, October 29, 2013; pages 64638-64690.